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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re United States Patent Application of:		**Docket No.:**	**4171-102 CIP**
Appellant:	**Jason C.H. SHIH**		
Serial No.:	**10/007,613**	**Art Group:**	**1648**
Date Filed:	**October 26, 2001**	**Confirm. No.:**	**4213**
Title:	**METHOD AND COMPOSITION FOR STERILIZING SURGICAL INSTRUMENTS**	**Customer No.:**	**23448**

EXPRESS MAIL CERTIFICATE

I hereby certify that I am mailing the attached documents to the Commissioner for Patents on the date specified, in an envelope addressed to Mail Stop Appeal Brief – Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 and Express Mailed under the provisions of 37 CFR 1.10.

Candace White

March 20, 2006
Date

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REPLY BRIEF FILED PURSUANT TO 37 CFR §1.193(b)(1) IN RESPONSE TO THE JANUARY 19, 2006 EXAMINER'S ANSWER IN U.S. PATENT APPLICATION NO. 10/007,613

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This reply brief is filed under the provisions of 37 CFR §1.193(b)(1), and responds to the Examiner's Answer dated January 19, 2006 in this appeal.

STATUS OF CLAIMS

The status of the appealed claims 39-51, 53-56, 63, 71, 73-74, 80 and 82 has not changed during the pendency of this appeal, and all such claims remain rejected on the grounds discussed in Issue #2 in the subsequent section.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL—ISSUES ADDRESSED IN THIS REPLY BRIEF

The following issues are addressed in this Reply Brief, in response to the Examiner's Answer:

Issue #1

Whether the Examiner's position on propriety of recital of articles in the claimed system of claims 39-51, 53-56, 63, 71, 73-74, 80 and 82 is a non-appealable issue.

Issue #2

Whether appellant's claims 39-51, 53-56, 63, 71 and 73 are obvious over the WHO reference ("WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies: Report of a WHO Consultation," World Health Organization (WHO), March 23-26, 1999 (hereinafter "WHO Document"), esp. pages 14 and 29), in view of the teachings of Huth (U.S. Patent 6,448,062), Vlass (U.S. Patent 6,210,639) and Potgeiter (Statutory Invention Registration H001818), and further in view of the teachings of Bolton (Bolton et al., "Molecular Characteristics of the Major Scrapie Prion Protein," Biochemistry, Vol. 23 No. 25 (December 1984), pages 5898-5906) and Oesch (Oesch et al., "Properties of the Scrapie Prion Protein: Qualitative Analysis of Protease Resistance, Biochemistry, Vol. 33 No. 19 (May 1994), pages 5926-5931), and Shih (U.S. Patent 5,171,682) [Shih et al being applied to claims 74, 80 and 82 as an additional citation].

ARGUMENT

Issue #1

Whether the Examiner's position on propriety of recital of articles in the claimed system of claims 39-51, 53-56, 63, 71, 73-74, 80 and 82 is a non-appealable issue.

The Examiner has contended that the issue of propriety of recitation of articles in the claimed system presents a non-appealable issue that should instead be petitioned for resolution under the provisions of 37 CFR 1.181.

Appellant's contention is to the contrary—it is submitted that the recitation of the "articles" is sufficiently related to the §103(a) rejection on the merits that it should properly be considered by the Board of Patent Appeals and Interferences in the present instance.

For ease of discussion, representative claim 39 is set out below in its entirety.

> 39. A system comprising:
> (a) one or more articles susceptible to contamination by infectious prion protein;
> (b) means for heating said articles;
> (c) a proteolytic enzyme selected from the group consisting of keratinases and subtilisins; and
> (d) means for exposing said articles to said proteolytic enzyme, wherein said one or more articles are characterized by a first elevated temperature of at least 40°C and not more than about 150°C during a first duration, wherein said articles are characterized by a second elevated temperature in a range of from about 50°C to about 65°C and exposure to said proteolytic enzyme during a second, subsequent duration.

The Examiner's contention therefore relates to the recital of "one or more articles susceptible to contamination by infectious prior protein." The full text of the Examiner's statement from the June 30, 2004 final Office Action is set out below:

> "these claims read on systems for the treatment of articles that may be infected with prion proteins. However, the systems are described in the claims as comprising the articles to be worked

> on by the apparatus. Because the articles so infected are to be treated by the system, it is inappropriate to include the articles in the claims system as they are not deemed to impart patentability to the system."

In response, it is pointed out that the Examiner in his §103(a) rejection of the claims has relied on the recital in the claim of the articles to be treated (Reply Brief, page 4, line 14), and the Examiner then discusses such articles in terms of the substantive basis of rejection. Accordingly, it is appropriate for the Board to consider the Examiner's position in its entirety, for economy of disposition. Appellant is not aware of any basis in the Patent Law, Title 37 of the Code of Federal Regulations, or the MPEP that would bar claiming of a system including articles that are transformed in the operation of the system.

In the operation of the claimed system as set forth in claim 39, the articles in the operation of the system would be transformed from a state of being actually or potentially infected with prion protein, to a reduced contamination state.

This circumstance is no different than the recital of a system for chemical processing that is directed to an electrochemical plating technology, in which the claimed system recites a bath of specified plating chemical, and platable work pieces.

The Examiner has not provided any authority or basis for his contention that the claims are improper. Substantively, this is a denial of the appellant's ability to state what he considers to be his invention, consistent with the provisions of 35 USC §112, second paragraph:

> "The specifications shall include with one or more claims particularly pointing out and distinctively claiming the subject matter which the applicant regards as his invention."

The statute therefore enjoins the patent applicant to specify the invention that is contemplated by him. While the claims must otherwise comply with the Patent Law, Title 37 of the Code of Federal Regulations and the MPEP provisions, nowhere is there any basis for characterizing appellant's claims (as exemplified by representative claim 39), as improper.

Issue #2

Whether appellant's claims 39-51, 53-56, 63, 71 and 73 are obvious over the WHO reference ("WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies: Report of a WHO Consultation," World Health Organization (WHO), March 23-26, 1999 (hereinafter "WHO Document"), esp. pages 14 and 29), in view of the teachings of Huth (U.S. Patent 6,448,062), Vlass (U.S. Patent 6,210,639) and Potgeiter (Statutory Invention Registration H001818), and further in view of the teachings of Bolton (Bolton et al., "Molecular Characteristics of the Major Scrapie Prion Protein," Biochemistry, Vol. 23 No. 25 (December 1984), pages 5898-5906) and Oesch (Oesch et al., "Properties of the Scrapie Prion Protein: Qualitative Analysis of Protease Resistance, Biochemistry, Vol. 33 No. 19 (May 1994), pages 5926-5931), and Shih (U.S. Patent 5,171,682) [Shih et al being applied to claims 74, 80 and 82 as an additional citation].

For ease of reference, the representative claim 39 is again set out below:

> 39. A system comprising:
>
> (a) one or more articles susceptible to contamination by infectious prion protein;
>
> (b) means for heating said articles;
>
> (c) a proteolytic enzyme selected from the group consisting of keratinases and subtilisins; and
>
> (d) means for exposing said articles to said proteolytic enzyme, wherein said one or more articles are characterized by a first elevated temperature of at least 40°C and not more than about 150°C during a first duration, wherein said articles are characterized by a second elevated temperature in a range of from about 50°C to about 65°C and exposure to said proteolytic enzyme during a second, subsequent duration.

The Examiner in his remarks in the Reply Brief (in the paragraph bridging pages 4 and 5 thereof) has disparaged the recital of the temperature condition of the articles included within the system, stating specifically that such limitations "would not be sufficient to distinguish the claimed system from the prior art so long as the systems taught by the prior art would be capable of performing the method steps."

In response, it is pointed out that appellant's claim 39 recites no method steps, but rather recites a system comprising articles that are characterized as to their physical state in the system. The Examiner therefore has mischaracterized the recital in the final paragraph of appellant's representative claim 39, stating in

essence that such claim would not patentably distinguish over the prior art if the prior art systems "would be capable of performing the method steps." This is an improper statement of rejection, and finds no basis in the patent statute, regulations, MPEP or applicable case law. In sum, there is no "capability" test for determining patentability of a recited system.

Concerning the merits of the Examiner's rejection, the primary WHO reference has been cited for disclosure at pages 14 and 29 relating to decontamination of instruments. As stated at page 14, lines 20-25, thereof:

> "If instruments are cleaned before decontamination, the cleaning materials must be treated as infectious waste, and the cleaning station must be decontaminated by one of the methods listed in Annex III. The instruments are then treated by one of the decontamination methods recommended in Annex III before reintroduction into the general instruments sterilization processes."

Annex III at pages 29-31 discloses "Decontamination methods for Transmissible Spongiform Encephalopaties," and states in the first paragraph thereof, at lines 1-3, that

> "The safest and most unambiguous method for ensuring that there is no risk of residual infectivity on contaminated instruments and other materials is to discard and destroy them by incineration."

The Annex then goes on to discuss autoclave/chemical methods for heat-resistant instruments as including bleach (sodium hypochlorite) and sodium hydroxide solutions in which the instruments are autoclaved at specified temperatures.

There is no disclosure of any enzymatic decontamination techniques or materials in the cited text of the WHO reference. Contrariwise, the WHO reference teaches away from any such enzymatic approach, by teaching incineration or alternatively autoclave/chemical (bleach or soda lye chemical disinfection techniques).

The secondary references have been cited as teaching enzymatic methods, yet none of such secondary references provides any motivation for alteration of the WHO reference techniques to yield appellant's claimed invention.

The secondary reference Huth has been cited for disclosure at columns 14 and 15 thereof of enzymes for cleaning and decontaminating devices, including disclosure of keratinase and subtilisin. There is, however, no teaching in Huth of any utility for the disclosed enzymes in decontamination of articles infected by prion protein, and *a fortiori*, no disclosure of utilizing specific temperatures for prion protein decontamination.

Vlass has been cited for disclosure therein at column 1, lines 49 and 50, column 2, lines 22-28 and column 5, as providing "[S]imilar teachings" to Huth (page 5, third paragraph of the Reply Brief), but Vlass contains no teaching or disclosure of prion protein disinfection, and further, and likewise in relation to Huth, does not disclose temperature conditions applicable to decontamination of prion protein infection or contamination. Since Vlass is expressly oriented to disinfection and cleaning of contact lenses, as representative of articles and devices with which the enzymatic composition therein disclosed may be used, it appears that the enzymatic compositions of such reference are utilized at ambient (room) temperature, further underscoring the lack of basis in such secondary reference for modification of the WHO reference disclosure, and lack of derivative basis for appellant's claimed invention.

Potgeiter has been cited for disclosure at columns 14-15 and column 16 at lines 40-47, but again such reference does not address any decontamination from infectious prion protein, or therefore, it does not disclose any temperature conditions applicable to prion protein decontamination.

Accordingly, the WHO reference, in combination with Huth, Vlass and Potgeiter, provides no basis whatsoever for appellant's claimed invention.

The Examiner in the paragraph bridging pages 6 and 7 of the Reply Brief then states that the additional teachings of Bolton and Oesch provide the skilled person in the art with reasonable expectation of success.

Concerning the citation of Bolton by the Examiner, it is to be appreciated that Bolton is not directed to attacking infectious prion protein in animal tissue, but rather involves the characterization of purified (isolated) scrapie prion protein in a buffered solution of sodium dodecyl sulfate (SDS) and 2-mercaptoethanol. Respective samples of the SDS/2-mercaptoethanol solution containing the isolated scrapie protein were heated to 25°C, 37°C, 65°C and 100°C for 2 minutes, then cooled to room temperature, following which proteinase K was added to the SDS/2-mercaptoethanol solution.

The *solution* behavior of purified scrapie described in Bolton is not in any way predictive of or extrapolative to the appellant's claimed system including keratinase or subtilisin proteolytic enzyme and articles susceptible to contamination by infectious prion protein – Bolton discloses proteinase K used in a room temperature solution.

Bolton's disclosure therefore provides no basis for use of any other enzyme other than proteinase K, and there is no teaching or suggestion in such reference to effect enzymatic activity at elevated temperature, since Bolton uses a very different enzyme at room temperature.

Accordingly, and contrary to the Examiner's characterization, Bolton does not provide any motivational basis for modifying the WHO reference in combination with Huth, Vlass and Potgeiter to yield appellant's claimed invention.

The further reference of Oesch has been cited for disclosure at page 5928 thereof, which the Examiner characterizes as "indicating that prions become susceptible to protease degradation after being denatured" (page 6, lines 20-21 of the Examiner's Answer). In fact, this characterization of the reference teachings misstates the actual disclosure in such reference. Oesch actually states that

> "We [Oesch et al] suspect that endogenous proteases degrade PrP^C in the native sample during the incubation at 37°C, and that these proteases may be inactivated in the samples first denatured in GdnSCN."

Thus, Oesch contains only speculation ("[W]e suspect that....")

In addition to the fact that Oesch is merely a speculative observation, it is to be noted that Oesch is directed to proteinase K, and there is no teaching or suggestion of the keratinase or subtilisin required in appellant's claimed system.

Oesch therefore provides no motivational basis for modification of the disclosures of the WHO reference in view of Huth, Vlass, Potgeiter and Bolton. Indeed, in view of the teaching away of the primary

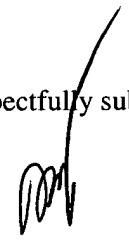
reference (the WHO reference), the non-disclosure of prion decontamination by the enzymatic species required in appellant's claimed system and the failure of the cited references in combination to teach or suggest all elements of appellant's claimed invention, it is apparent that the rejection on the stated grounds is in error, and should be reversed by the Board.

The Shih reference further applied in combination with the WHO reference, Huth, Vlass, Potgeiter, Bolton and Oesch (against claims 74, 80 and 82) contains no mention of prion decontamination or degradation, and therefore provides no remedial basis for curing the deficiency of the combination of the WHO reference, Huth, Vlass, Potgeiter, Bolton and Oesch.

The Examiner's further commentary ("Response to Argument") at pages 7-10 of the Reply Brief does not alter the fact that the appellant's invention as claimed finds no derivative basis in the cited references, and that appellant's claims are fully proper in form and substance.

Based on all of the foregoing, the Board of Patent Appeals and Interferences therefore is respectfully requested to reverse the decision of the Examiner finally rejecting the claims here appealed, and to remand the application to the Examiner for further action consistent with such reversal of the final rejection of such claims.

Respectfully submitted,



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